NEW YORK PHARMA FORUM

TUESDAY, JANUARY 28, 2014

TOPIC: **Beyond Breakthrough: The New Look of FDA Expedited Review Programs**

SPEAKERS: **Diane Beatty**, PhD, Director, Managing Consultant, Beckloff Associates
Steven Fruchtman, MD, Chief Medical Officer, Syndax Pharmaceuticals Inc.
Robert Ryan, PhD, Chief Executive Officer, Scioderm, Inc.

For many years, the FDA has provided expedited pathways to shorten the time of development and review for new drugs that address unmet medical needs in the treatment of serious conditions. Drugs approved through expedited review programs—such as fast track designation, accelerated approval, and priority review—undergo an average of about 5 years of clinical testing, compared to almost 8 years for those that go through standard reviews, according to a recent study in the Journal of the American Medical Association (Thomas Moore, 2013).

With the passage of the FDA Safety and Innovation Act of 2012 (FDASIA), Congress introduced a fourth expedited review program, known as breakthrough therapy designation. This designation gives the FDA and drug developers more leeway in designing trials—such as consolidating the first two phases of the trials into just one—and allows these companies to receive more intensive guidance from the FDA throughout the development process. Since FDASIA was passed, the FDA has received more than 117 requests for breakthrough-therapy designation and has granted 35 of these requests.

At this program, Dr. Beatty will start by examining each of the FDA's four expedited review programs, and Drs. Fruchtman and Ryan will discuss their companies' experiences in achieving breakthrough therapy designation for their drug candidates. This will be an excellent opportunity to hear case examples from these innovative companies, exploring their decision making in pursuing the breakthrough designation, along with some of the challenges and opportunities they have faced throughout the process.